510(K) SUMMARY
InfraReDx LipiScan™ IVUS Imaging System

JUN 30 2010

Submitter Name:	InfraReDx, Inc.
Submitter Address:	34 Third Avenue Burlington, MA 01803
Contact Person:	Steven J. Chartier, Vice President, Clinical & Regulatory Affairs
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Date Prepared:	December 23, 2009
Device Trade Name:	InfraReDx LipiScan™ IVUS Imaging System
Device Common Name:	Near Infrared/IVUS Imaging System
Predicate Devices:	InfraReDx LipiScan™ IVUS Imaging System (K072932) Boston Scientific iLab Ultrasound Imaging System (K051679), Boston Scientific Atlantis SR Pro Catheter (K050577)
Device Description:	The InfraReDx LipiScan™ IVUS Imaging System is comprised of the catheter, catheter accessories, pull-back and rotation device and laser console with accessories.
Intended Use:	The LipiScan™ IVUS Imaging System is intended for the near-infrared examination of coronary arteries in patients undergoing invasive coronary angiography. a. The System is intended for the detection of lipid-core-containing plaques of interest. b. The System is intended for the assessment of coronary artery lipid core burden. The System is intended for ultrasound examination of coronary intravascular pathology. Intravascular ultrasound imaging is indicated in patients who are candidates for transluminal coronary interventional procedures.

Device Technology Characteristics and Comparison to Predicate Device:

The InfraReDx LipiScan™ IVUS Imaging System utilizes the same basic catheter design as the predicate, the InfraReDx LipiScan™ Coronary Imaging System, Gen. 1.0 cleared K072932. These devices have a similar intended use, use the same operating principal, incorporate the same basic catheter design, have the same shelf life, and are packaged using the same materials and processes. The modifications from the InfraReDx LipiScan™ Coronary

Imaging System, Gen. 1.0 to the InfraReDx LipiScan™ IVUS Imaging System are the inclusion of ultrasound imaging within the same dimensions of the catheter, and the additional testing required to support an expanded indication for use. The ultrasound capabilities are functionally equivalent to the Boston Scientific iLab System (K051679).

Performance Data:

Non-clinical Test Results

Bench, electrical safety and acoustic output safety testing demonstrate that the LipiScan™ IVUS System and its accessories meet or exceed performance requirements and is safe and effective for its intended use.

Bench Testing
Bench testing was performed to evaluate the performance and functionality of the LipiScan™ IVUS System. This testing included hardware unit-level tests, software unit-level test, and system level tests. The results demonstrate that the device satisfies all performance and functional requirements.

Electrical Safety Testing
The LipiScan™ IVUS System complies with EN 60601-1 and EN 60601-1-2 standards as verified by independent test facilities. The LipiScan™ IVUS System software was verified and validated in accordance with applicable FDA guidance documents.

Acoustic Output Testing
Acoustic output testing for the LipiScan™ IVUS System has been performed in accordance with FDA Guidance, *"Information for Manufactures Seeking Market Clearance of Diagnostic Ultrasound Systems and Transducers"*, issued September 30, 1997.

Conclusion:

The InfraReDx LipiScan™ IVUS Imaging System has similar indications statements as the predicate devices. All are used for imaging of the coronary vasculature. The functionality of the InfraReDx LipiScan™ IVUS System and predicate devices is equivalent. The catheter accesses the coronary vasculature via the femoral or radial access site and tracks on the existing guidewire as used during routine PCI. The device output is an image of the artery wall, as an adjunct to coronary angiography, and is similar to the predicate devices. *Ex vivo* and *in vivo* data is presented to support expanded indications for use. Therefore the

InfraReDx LipiScan™ IVUS Imaging System is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JUN 30 2010

InfraReDx, Inc.
C/O Steven J. Chartier
Vice President, Clinical and Regulatory Affairs
34 Third Avenue
Burlington, MA 01803-4414

Re: K093993
Trade/Device Name: LipiScan IVUS Imaging System
Regulation Number: 21 CFR 870.1200
Regulation Name: Diagnostic Intravascular Catheter
Regulatory Class: Class II
Product Code: OGZ, OBJ, IYO
Dated: May 21, 2010
Received: May 24, 2010

Dear Mr. Chartier:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K093993

Device Name: InfraReDx LipiScan™ IVUS Imaging System

Indications for Use:

1. The LipiScan™ IVUS Imaging System is intended for the near-infrared examination of coronary arteries in patients undergoing invasive coronary angiography.
    a. The System is intended for the detection of lipid-core-containing plaques of interest.
    b. The System is intended for the assessment of coronary artery lipid core burden.
2. The System is intended for ultrasound examination of coronary intravascular pathology.
    a. Intravascular ultrasound imaging is indicated in patients who are candidates for transluminal coronary interventional procedures.

Prescription Use __X__ AND/OR Over the Counter Use _____
(21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K093993

Indications for Use Table

System: LipiScan™ IVUS Imaging System
System Model: MC7
Transducer Model: 40 MHz IVUS

Clinical Application		Mode of Operation						
General	Specific	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-Operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (Conventional)							
	Musculo-skeletal (Superficial)							
	Intravascular							
	Other							
Cardiac	Cardiac Adult	X						
	Cardiac Pediatric							
	Intravascular (Cardiac)	X						
	Trans-esoph. (Cardiac)							
	Intra-Cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel							
	Other (Specify)							